



DECLARATION OF CONFORMITY

Manufacturer's Name: Invivo Corporation
Manufacturer's Address: 12501 Research Parkway
Suite 100
Orlando, FL 32826
USA

Declares, that the product

Product Name: 4500MRI Pulse Oximeter

Model Number(s): 3109-3

Starting Revision, Date code, SN, Lot Number: January, 1993

Product Options: Stand-Alone Pulse Oximeter
Language Options

to which this declaration relates is in conformity with Annex I Essential Requirements of the Council Directive:

93/42/EEC (LVFS 2003:11)

“Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices” (Medical Device Directive).

The Manufacturer is certified by Intertek ETL SEMKO AB (0413) to EN ISO 13485 and Annex II-Section 3.2 of Directive 93/42/EEC. Copies of the Quality System certificates are available upon request.

The product is Class IIb according to Annex IX of Directive 93/42/EEC.

The Global Medical Device Nomenclature Code (GMDN) is 37770.

Supplementary Information:

The product was tested in a typical configuration as described in the Manufacturer's accompanying documents.

Add standards here :

EN 60601-1, EN 60601-1-2, EN 60601-1-4, EN 60601-1-8, EN ISO 9919, EN ISO 10993-1, EN ISO 14971

Orlando, 23 May, 2008

Rusty Kelly
Quality and Regulatory Manager
Invivo Corporation

Authorized EU-representative: Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany

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